SEVEN COUNTIES SERVICES, INC.

Instructions For Submitting A Research Proposal For Review

1. Complete the attached General Information Sheet. (Please use the form provided on the following pages.)

2. Include a copy of the researcher(s) vita or resume.

3. Include a letter from the Division Director who has authority over the area where the research will be conducted, granting permission to conduct the research.

4. Prepare a description of the research study by answering the questions listed on form listed in the following pages. **Please provide a clearly stated Hypothesis and research objective.**

5. Read carefully the Instructions for Documentation of Informed Consent, which are included in this document. Prepare and include a copy of the consent forms proposed to be used.

6. If the research project involves subjects under the age of eighteen (18), read carefully the description of requirements for research involving children. If appropriate, prepare the consent form that will be used.

7. If the research involves a survey or interview procedure, the questionnaire, interview questions, or assessment scale should be included in the application.

8. Before submitting the application to the Research Committee, the requested information must be organized in the following order:

   a. General Information Sheet;
   b. Investigator(s) Vita (Resume);
   c. Research Description Summary;
   d. Documentation of Informed (Parental) Consent;
   e. Assent Form, if applicable;
   f. Instrument to be used for data collection, if applicable.

9. Submit the above materials to the Research Committee in care of Ron Van Treuren, Ph.D., Chair of the Research Committee, 317 Taylorsville Rd., Louisville, KY, 40220-1366. Pony address: TOC School Based Services. Email: rvantreu@sevencounties.org Please be advised, SCS provides liability insurance covering research activities only for SCS employees.

SEVEN COUNTIES SERVICES, INC.
IRB
GENERAL INFORMATION SHEET

NAME OF PRINCIPAL RESEARCHER:
EMAIL:

ADDRESS:
CITY: STATE: ZIP:

PHONE NUMBER: FAX:

FACULTY ADVISOR (IF APPLICABLE):

TITLE OF PROJECT:

ANTICIPATED BEGINNING DATE: COMPLETION:

WHERE IS THE RESEARCH TO BE CONDUCTED? (I.E., SCS SITE):

HAVE YOU CONTACTED THE DIVISION DIRECTOR RESPONSIBLE FOR THAT SITE? ☐ YES ☐ NO

I agree by my signature to provide SCS with a copy of my completed research (including an abstract) and to reference SCS in any publication(s) of the research.

Signature Date

SEVEN COUNTIES SERVICES, INC.
RESEARCH DESCRIPTION FOR IRB REVIEW

*In preparing the research description, briefly answer the questions listed below. If the items do not apply to your research project, simply indicate the question is not applicable.*

1. List research objectives:

2. Clearly state your hypothesis and research objective:

3. Briefly describe past experimental and/or clinical findings and review of related literature leading to the formulation of the study.

4. Describe the characteristics of the subject population:

   Anticipated number of subjects:
   Age range:
   Gender:
   Ethinic Background (if applicable):
   Health Status (if applicable):
   Other:

5. Describe plans for recruitment of subjects and consent procedures to be followed, including the circumstances under which consent will be obtained and documented:

6. Describe any concessions that have been made in selecting the sample for study that could adversely affect the utility/validity of any findings (e.g., selection of subjects limited by clinical consideration.)

7. Describe the study design:

8. Describe the research procedures that will be followed. Identify all procedures

that will be carried out with each type of subject.

9. Describe the procedures for protecting against, or minimizing, any potential risk, including risk of breach of confidentiality.

10. Discuss why the risk to subjects is reasonable in relation to the anticipated benefit to the subjects.

11. Describe the incentives being offered to the subjects for participating in the research study.

SEVEN COUNTIES SERVICES, INC.

INSTRUCTIONS FOR THE

DOCUMENTATION OF INFORMED CONSENT

*Informed consent is a primary ethical justification for research with human subjects and is an on-going educational process that takes place between the investigator and prospective subject. It is not simply a piece of paper that must be signed in a discreet moment in time. Below are listed instructions for preparing the written consent form (all of the information must be contained within already prepared forms). Please follow them carefully.*

1. The consent form should be written in language the subject can understand.

2. Include a heading as follows: "Consent for Research Study", followed by the exact title of the proposed study.

3. In the first paragraph of the consent form include the following statement (delete any portions of this statement that are not applicable to your study):
"I, _____, agree to participate in the research study under the direction of Dr._____ and _____ along with the medical supervision of Dr. _____. I understand that while the study will be under the supervision of Dr.'s_____ and _____ other professional persons who work with them may be designated to assist or act in their behalf."

4. Include an explanation of the purpose of the research.

5. Include an explanation of the expected duration of the subject's participation, and location of the project.

6. Describe the procedures to be followed, including time involved and physical requirements. Identify any procedures that are experimental. If applicable, indicate whether the subject will be required to return for follow-up examinations/ procedures.
7. Describe any benefits to the subject that reasonably may be expected from the research.

8. Describe appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

9. Describe the extent to which confidentiality of records identifying the subject will be maintained and protected.

10. Include an explanation as to whether any compensation for participation in the study will be provided. Specify the nature of this compensation.

11. Include the following statement: "I understand that in the event of injuries resulting from the research procedures in which I am to participate, no form of compensation is available. Medical treatment may be provided at my own expense or at the expense of my health care insurer (i.e. Medicaid, Medicare, Blue Cross/Blue Shield, etc.) which may, or may not, provide coverage. If I have any questions, I should contact my insurer."

12. Include an explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research related injury to the subject. **Indicate the subject will receive a copy of the consent form**.

13. Include the following statement: "Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled. I understand I may discontinue my participation at any time without penalty or loss of benefits to which I am otherwise entitled."

14. When appropriate, one or more of the following elements of information should be included on the consent form:
    a. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
    b. Any additional cost to the subject, which may result from participation in the research;
    c. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
    d. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject;
    e. The approximate number of subjects involved in the study.

15. Provide a place for:
    a. Signature of the subject (or the legally authorized representative);
    b. The date of that signature;
    c. Signature of the witness;

16. Include the following statement in the accompanying provision for the principal investigator signature.

    "I have explained and defined in detail the research procedure in which the subject has consented to participate."

    _____
    Principal Investigator Date

17. If the research involves the participation of minors [under eighteen (18) years of age], please read the Description of Requirements for Research Involving Children, which is attached.

SEVEN COUNTIES SERVICES, INC.
DESCRIPTION OF REQUIREMENTS
FOR RESEARCH INVOLVING CHILDREN

Children are considered a vulnerable research population because their intellectual and emotional capacities are not yet fully developed and they are legally incompetent to give valid consent. Special procedures and considerations are therefore required for research involving children. The Research Committee is required to consider the degree of risk in the proposed research and the methods for obtaining the assent of children, as well as permission of parents or legal guardians. The Research Committee's policy with respect to obtaining consent and assent from minors is specified below:

1. In most cases parental consent must be obtained if the research involves minors under the age of eighteen (18). The following sections of the Informed Consent Form would be amended as noted to document parental consent:

   (1) Include a heading as follows: "Parental Consent for Research Study," followed by the exact title of the proposed study.

   (2) "I/We, (Names of both Parents, or Custodial Parent), agree for (Name of child), to participate in the research study under the direction of Dr. and _____ along with the medical supervision of Dr._____, I/we understand that while the study will be under the supervision of Dr.'s and _____ other professional persons who work with them may be designated to assist or act in their behalf."

   (3) "I understand that in the event of injuries resulting from the research procedures in which my child is to participate, no form of compensation is available. Medical treatment may be provided at my/our own expense or at the expense of my/our health care insurer (i.e., Medicaid, Medicare, Blue Cross/Blue Shield, etc.) which may, or may not, provide coverage. If I/we have any questions, I/we should contact my/our insurer.

   (4) "Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which my/our child is otherwise entitled. I/we understand I/we may discontinue my/our child's participation at any time without penalty or loss of benefits to which my/our child is otherwise entitled".

   (5) Both parents (or the custodial parent) must sign the consent form, unless the Research Committee waives this requirement.

2. Subjects six (6) years of age or older should be involved in the decision to participate in the research project unless the subject is incapable mentally or emotionally of being reasonably consulted, or the Research Committee specifically waives this requirement.
3. Unless the IRB waives the requirement, documentation of assent is essential for subjects age twelve (12) to eighteen (18). In most cases a written assent form should be used to document the assent. A copy of the assent must be submitted for review to the Research Committee in addition to the informed consent form. The form must be constructed by the investigator, and should include a simplified version of the elements of informed consent, which are described in the Instructions for the Documentation of Informed Consent. Note that the child should be given an explanation (at a level appropriate to the child's age, and maturity) of the condition(s) or procedure(s) to be used, their meaning to the child in terms of discomfort, and any inconvenience that may result.

4. Appropriate arrangements attuned to the child's age and maturity must be planned to protect and avert any potentially harmful circumstances due to the research.